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### Biosimilars: Expanding the scope of biologic therapy through wider patient access

**Background:** Medicinal compounds are often organic compounds, which are divided into classes of small organic molecules and biologics. Chemical drugs are made of pure chemical substances and their structures can be identified. Biologics are made from natural sources and are used to treat medical conditions. Most biologics, however, are complex mixtures that are more difficult to identify. They have larger molecules than small molecule drugs. "Biosimilar" is a term that is used for copy versions of biologics. There is more variation when trying to replicate a biologic drug than for drugs made by chemical synthesis, so, the term "biosimilar" is used instead of "generic". Biosimilar must have no clinically meaningful differences between it and the reference product it was compared to in terms of the safety and potency.

**Issue:** The clinical applications of biosimilars remain under-recognized by several physicians across the globe.

**Objective:** The aim of the research is to provide a comprehensive review of biosimilars and its potential therapeutic applications in clinical practice.

**Methods:** Current literature were analyzed, summarized and interpreted to present biosimilars clinical applications.

**Results:** Some biologics will lose patent protection during the coming few years and could be replaced with lower cost biosimilars. Regulatory guidelines for development and approval are becoming more rigorous. As a prerequisite, the approval process requires solid demonstration of comparability in quality, efficacy, and safety between the biosimilar and the reference product.

**Conclusions:** A great potential still exist for biosimilars to expand biologic therapy through better patient access across many therapy areas. A much wider access compared with biologics due to better affordability could be a clear advantage for a biosimilars in the near future.

### Biography

Ahmed Radwan has received his MSc and Doctoral degrees from Middlesex Business School in London. He also holds a first degree in Pharmacy and Pharmaceutical Sciences from Cairo University. He is an Adjunct Professor of Management at Edinburgh Business School, Herriot Watt University in the UK. He is also the Chairman and CEO of Pioneera HealthCare Group. He has over 25 years of experience within the pharmaceutical sector, including ethical pharmaceuticals, OTC, generics and strategic management consultation in the pharmaceutical field. He was the Marketing Director of Novartis, Regional Marketing Director of Otsuka and Regional Marketing Director of GSK.

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